medical CV™

MAR 16 2007

Section II

Summary of Safety and Effectiveness (as required by 21 CFR 807.92)

Solar™ Surgical Ablation System (K061489)

Submitter: MedicalCV, Inc.
9725 South Robert Trail
Inver Grove Heights, MN 55077
USA

Contact: Denny Steger
V.P. RA/QA
Phone: 651 452 3000
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Date of Summary: March 8, 2007

Classification Name: Laser Instrument, Surgical Powered

Common Name: Surgical Laser Instrument

Proprietary Solar™ Surgical Ablation System

Description of Device: The Solar™ Surgical Ablation System consists of a Laser Energy Generator, a Reciprocator Control unit, a fluid delivery tubing set and a flexible surgical ablation track. The Solar™ Orbital Track is an intraoperative, sterile, single-use device designed to apply laser energy to tissue. The fluid delivery tubing set is a single-use device having a sterile fluid path designed for the delivery of sterile saline solution to the ablation catheter. The Reciprocator Control unit is a motion generating device housing the fluid delivery pump and provides the means of monitoring the ablation process parameters. The laser energy Generator and Reciprocator Control Unit are sold separately. The Solar™ Orbital Track includes a ridged metallic shaft, a flexible track, and a guide lead and is equipped with a 905 SMA connector cable which attaches to the laser energy generator output connector. The emitted laser energy is directed toward the target tissue from the end of the optical fiber which rides within the flexible track.

Statement of Intended Use: The Medical CV Solar™ Surgical Ablation System is indicated for delivery of 810nm or 1064nm laser light to soft tissue, under direct visualization, during surgical procedures. Indications include the ablation, or coagulation of soft tissue.

Warning: The Solar™ Surgical Ablation System is not indicated for the treatment of cardiac arrhythmias.

The risk of actual damage to adjacent organs from the instrument exists and perforation, rupture or tearing of tissue, may occur as a complication of laser use. Burns can occur if the laser energy is not correctly applied. These complications may be serious.

Technological Comparison: The Solar™ Surgical Ablation System was compared to the current Atrilaze™ Surgical Ablation System and Guidant's FLEX10 Surgical Ablation System.

Both the currently available Atrilaze™ ablation probe and the Solar™ flexible Orbital Track are provided sterile with a sterile, non-pyrogenic fluid path used for cooling of the optical fiber. Both fiber optic delivery systems utilize the same laser energy generator and are connected via an SMA 905 connector to deliver laser energy to the target tissue.

Both the Solar™ Surgical Ablation and the Guidant FLEX10 Surgical Ablation Systems employ a flexible track/catheter and are positioned using existing endoscopic tools and techniques and are monitored under direct visualization by the surgeon during use.

For purposes of this submission, the Solar™ Surgical Ablation System was compared to the following predicate devices:

- Medical CV Atrilaze™ Surgical Ablation System (K040744, K052495 & K060680)
- Guidant's Microwave FLEX10 Surgical Ablation System (K003978 & K013946)

Testing: The results of biocompatibility testing conducted on the disposable fiber optic delivery system and tubing set support that the materials used in the manufacture of the disposables are non-toxic, non-hemolytic, and non-pyrogenic. All biocompatibility testing was conducted under Good Laboratory Practices per 21 CFR Part 58.

Performance testing for the Solar™ Surgical Ablation System included compliance to manufacturing specifications for Power Output, Fluid Flow along with visual and histology evaluation of the lesions obtained on cardiac tissue.

Testing demonstrated that adherence to specifications was demonstrated and the lesions obtained using the Solar™ flexible Orbital Trac are substantially equivalent to those obtained with the currently cleared Atrilaze™ Surgical Ablation System, ***which is to be expected since the energy source, the optical fiber, and application method used in both systems are identical***.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MedicalCV, Inc.
% Mr. Denny Steger
VP, RA/QA
9725 South Robert Trail
Inver Grove Heights, Minnesota 55077

MAR 16 2007

Re: K061489
Trade/Device Name: SOLAR™ Surgical Ablation System
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: II
Product Code: GEX
Dated: January 17, 2007
Received: January 18, 2007

Dear Mr. Steger:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

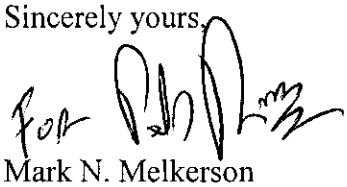
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(K) Number: K061489

Device Name: SOLAR™ Surgical Ablation System

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Prescription Use__X__ OR Over-the-Counter Use____
(Per 21 CFR 801.109)

(Please do not write below this line – Continue on another page if necessary)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices

510(k) Number K061489